IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
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In re

Patent Application of

Craig E. Smith, et al.

Serial No.: Unknown

Filed: Herewith

Examiner: Unknown

CERTIFICATION UNDER 37 CFR 1.10

I, Leslie Lindsay, hereby certify that this correspondence is being deposited with the United States Postal Service in an envelope as "Express Mail Post Office to Addressee," mailing Label Number EL832142007US, addressed to United States Patent and Trademark Office, BOX PATENT APPLICATION, COMMISISONER OF PATENTS, WASHINGTON, D.C. 20231.

Leslie Lindsay
Signature

January 7, 2002
Date

"METHODS AND KITS FOR ISOLATING BIOLOGICAL TARGET MATERIALS USING SILICA MAGNETIC PARTICLES"

PRELIMINARY AMENDMENT

BOX PATENT APPLICATION
Commissioner for Patents
Washington, D.C. 20231

Sir:

This application is a continuation of U.S. Patent Application Serial No. 09/459,502, filed under 37 CFR 1.53(b). Prior to examination on the merits, please amend the subject application as follows:

In the Specification:

Please delete the title and replace it with the following:

METHODS AND KITS FOR ISOLATING BIOLOGICAL TARGET MATERIALS USING SILICA MAGNETIC PARTICLES

Please delete the first full paragraph on page 1, which immediately follows "CROSS-REFERENCE TO RELATED APPLICATIONS", and replace it with the following:

This application is a continuation of U.S. Patent Application Serial No. 09/459,502, filed December 13, 1999, which is a divisional of U.S. Patent Application Serial No. 08/785,097, filed January 21, 1997, now U.S. Patent No. 6,027,945, issued February 22, 2000. Reference is made to U.S. Patent Application Serial No. 08/786,600, filed January 21, 1997 (international counterpart published as WO 98/31461 on July 23, 1998), entitled "Silica Adsorbent on Magnetic Substrate", which application is incorporated by reference herein in its entirety.

In the Claims:

Please cancel claims 7-21.

Please replace claims 1 and 22 with the following claims:

1. A method for isolating a biological target material from other material in a medium comprising the steps of:

(a) contacting the medium comprising the biological target material with silica magnetic particles capable of reversibly binding the biological target material to form a complex between the silica magnetic particles and the biological target material;

(b) removing the complex from the medium by application of an external magnetic field; and

(c) separating the biological target material from the complex by eluting the biological target material, whereby the isolated biological target material is obtained.

22. A method of isolating a plasmid DNA material from other materials in a medium comprising the steps of:

(a) forming a mixture comprising a medium comprising the plasmid DNA, a siliceous oxide-coated magnetic particle with the capacity to reversibly bind at least 2 micrograms of biological target material per milligram of particle, and a chaotropic salt, wherein the chaotropic salt concentration in the mixture is sufficiently high to cause the plasmid DNA to adhere to the particle;

(b) incubating the mixture at about room temperature until at least some of the biological target material is adhered directly to the siliceous oxide-coated magnetic particle;

(c) removing the siliceous oxide-coated magnetic particle from the mixture using an external magnetic force; and

(d) eluting at least 60% of the plasmid DNA adhered to the siliceous oxide-coated magnetic particle by exposing the particle to an elution solution.

Please add the following new claims:

31. The kit for isolating a biological target material according to claim 29, where in the particles directly and reversibly bind at least 2 micrograms of the biological target material per milligram of particle.

32. A kit for isolating a biological target material according to claim 31, wherein the siliceous oxide-coated magnetic particles have the capacity to release at least about 60% of the biological target material adhered thereto.

33. A kit for isolating a biological target material according to claim 31, further comprising:

a chaotropic salt in a second container; and

a wash solution in a third container.

34. A kit for isolating a biological target material according to claim 33, wherein the chaotropic salt is selected from the group consisting of guanidine hydrocholoride and guanidine thiocyanate.

35. A kit for isolating a biological target material according to claim 33, wherein the wash solution comprises a salt and a solvent.

36. A kit for isolating a biological target material according to claim 35, wherein said solvent is an alcohol.

37. A kit for isolating a biological target material according to claim 36, wherein the wash solution comprises said alcohol in a concentration of at least 30% by volume.

38. A kit for isolating a biological target material according to claim 36, wherein said alcohol is ethanol or isopropanol.

39. A kit for isolating a biological target material according to claim 35, wherein said salt is an acetate buffer.

40. A kit for isolating a biological target material according to claim 33, further comprising an elution solution in a fourth container.

41. A kit for isolating a biological target material according to claim 40, wherein the elution solution comprises an aqueous solution of low ionic strength buffered to a pH between about 6.5 and 8.5.

42. A kit for isolating plasmid DNA from a medium, the kit comprising:

an aliquot of siliceous oxide-coated magnetic particles suspended in an aqueous solution in a first container, wherein the particles have the capacity to directly and reversibly bind at least 2 micrograms of the plasmid DNA per milligram of particle.

43. A kit for isolating plasmid DNA according to claim 42, further comprising:

a wash solution in a second container;

a resuspension solution in a third container;

a neutralization solution in a fourth container; and

a cell lysis solution in a fifth container.

44. A kit for isolating plasmid DNA according to claim 43, wherein the wash solution comprises a salt and a solvent.

45. A kit for isolating plasmid DNA according to claim 44, wherein said solvent is an alcohol.

46. A kit for isolating plasmid DNA according to claim 45, wherein the wash solution comprises said alcohol in a concentration of at least 30% by volume.

47. A kit for isolating plasmid DNA according to claim 46, wherein said alcohol is ethanol or isopropanol.

48. A kit for isolating plasmid DNA according to claim 44, wherein said salt is an acetate buffer.

49. A kit for isolating plasmid DNA according to claim 48, wherein said chaotropic salt is a guanidinium chaotropic salt selected from the group consisting of huanidine hydrochloride and guanidine thiocyanate.

50. A kit for isolating plasmid DNA according to claim 43, wherein the resuspension solution comprises Tris-HCL, EDTA, and RNase A.

51. A kit for isolating plasmid DNA according to claim 43, wherein the neutralization solution comprises potassium acetate.

52. A kit for isolating plasmid DNA according to claim 43, wherein the cell lysis solution comprises NaOH and SDS.

53. A kit for isolating biological target material according to claim 33, wherein the first chaotropic salt and the second chaotropic salt are the same.

54. A kit for isolating plasmid DNA according to claim 43, further comprising a solution comprising a second chaotropic salt in a sixth container.

55. A kit for isolating plasmid DNA according to claim 54, wherein said second chaotropic salt is a guanidinium chaotropic salt consisting of guanidine hydrocholoride or guanidine thiocyanate.

56. A kit for isolating plasmid DNA according to claim 54, wherein the first chaotropic salt and the second chaotropic salt are the same.

Remarks:

With entry of the preliminary amendment, claims 1-6 and 22-56 are pending in the present application. The amendments are fully supported by the specification and claims of the priority document (U.S. Serial No. 08/785,097) and introduce no new matter.

Respectfully submitted,

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Marked up Copy of Amendments Showing Changes

In the specification:

In the title:

METHODS AND KITS FOR [OF] ISOLATING BIOLOGICAL TARGET MATERIALS USING SILICA MAGNETIC PARTICLES

Page 1, paragraph 1:

After "CROSS-REFERENCE TO RELATED APPLICATIONS":

This application is a continuation of U.S. Patent Application Serial No. 09/459,502, filed December 13, 1999, which is a divisional of U.S. Patent Application Serial No. 08/785,097, filed January 21, 1997, now U.S. Patent No. 6,027,945, issued February 22, 2000. Reference is made to [concurrently filed] U.S. Patent Application Serial No. 08/786,600, [_____] filed January 21, 1997, (international counterpart published as WO 98/31461 on July 23, 1998), entitled "Silica Adsorbent on Magnetic Substrate", which application is incorporated by reference herein in its entirety.

In the claims:

1. A method for isolating a biological target material from other material in a medium [by] comprising the steps of:

(a) contacting [providing] the medium comprising [including] the biological target material[; providing] with silica magnetic particles capable of reversibly binding the biological target material[; (b) forming] to form a complex of the silica magnetic particles and the biological target material [by combining the silica magnetic particles and the medium];

[(c)] (b) removing the complex from the medium by application of an external magnetic field; and

[(d)] (c) separating the biological target material from the complex by eluting the biological target material, whereby the isolated biological target material is obtained.

22. A method of isolating a plasmid DNA material from other materials in a medium comprising the steps of:

(a) forming a mixture comprising [providing] a medium comprising [containing] the plasmid DNA[; b) providing] a siliceous oxide-coated magnetic particle with the capacity

to reversibly bind at least 2 micrograms of biological target material per milligram of particle[; c) forming a mixture comprising the medium, the siliceous oxide-coated magnetic particle], and a chaotropic salt, wherein the chaotropic salt concentration in the mixture is sufficiently high to cause the plasmid DNA to adhere to the particle;

[d)] (b) incubating the mixture at about room temperature until at least some of the biological target material is adhered directly to the siliceous oxide-coated magnetic particle;

[e)] (c) removing the siliceous oxide-coated magnetic particle from the mixture using an external magnetic force; and

[f)] (d)eluting at least 60% of the plasmid DNA adhered to the siliceous oxide-coated magnetic particle by exposing the particle to an elution solution.